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USER GUIDE

Glucometer

BLOOD GLUCOSE

Monitoring

System



ISPRI)

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The most important function of your meter is to measure your blood glucose level. The Glucometer[®] ESPRIT[™] system is designed to make this task as simple as possible. The test is done in the **TESTING MODE** using a simple, integrated step.

The system also provides for those who want more detailed information like averages and other special features. All such options are provided in a separate mode called — the **FEATURES MODE.** The buttons on the instrument are only used for the additional features.

Because the options of the **FEATURES MODE** take more time to learn than the use of the **TESTING MODE**, we encourage you to go through the User Guide and decide what features are right for you to make your diabetes more manageable.



Meter Parts



CAUTION: Before using any product to test your blood glucose (sugar), read all instructions and practice the test. Do all quality control checks

as directed and consult with a diabetes health professional. These

and the Health Industry Manfacturers Association.

recommendations apply to all blood glucose monitoring systems and are supported by the American Association of Diabetes Educators,* the American Diabetes Association, the Food and Drug Administration

If you have any questions or concerns as you learn how to use the system, see Customer Service, page 34.

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CHAPTER Preview – There are two operation modes:

The Testing Mode



The Features Mode

The Features Mode is used to:

- set time/date
- set specific average times
- reset meter options
- review results
- erase test results
- transfer to a computer

NOTE: You can turn off Meter (move Slide back) at any time in Features Mode: any settings that have been changed are stored.

The Testing Mode is used to:

- run a blood glucose test
- run a control test



Important to know:

- Each Test Sensor Disc has ten Test Sensors.
- Each disc is assigned a Programme Number to assure accuracy in test results when the Meter is set to match that number.

Materials Needed:



Test Sensor Disc





1. Open the **Meter** by releasing the **End Latch**.







3. Before inserting the disc (bumpy side up), note the two blue **Meter Tabs** on the inside of the **Meter**.



Gently press the disc into place under the two Meter Tabs. Please note the Programme Number on your Test Sensor Disc.



Tabs

CHAPTER Inserting a Test Sensor Disc

Inserting a Test Sensor Disc 2

4. Close the Meter and fasten the End Latch.

You may now run ten tests before replacing the **Test Sensor Disc.**

5. After inserting a Test Sensor Disc, set the Programme Number. Move Slide forward to enter Features Mode. The Programme Number flashes in the display.

Press **Button B** to the **Programme Number** (P1 to P62) that matches the number you noted on the **Test Sensor Disc** (see cover foldout example) or end flap on **Test Sensor Carton.**

Press **Button A** to continue (set time/date) or move **Slide** back to turn **Meter** off.









To Remove the Used Test Sensor Disc: Open the Meter and lift the edge of the used Test Sensor Disc out from under the two blue Tabs and remove from the Meter.







Prepare for the Finger Puncture Materials Needed:

Microlet™ Device with Endcap Glucolanz™ Lancet

1. Remove the endcap.



- **2.** Insert lancet firmly until the lancet comes to a full stop then twist off lancet cap.
- **3.** Replace the endcap.

NOTE: See Microlet package insert for complete instructions.

4. Wash your hands with warm soapy water. Rinse and dry thoroughly.





Before running a test, **be sure**:

- The Test Sensor Disc is inserted. See page 1.
- The date and time are set (if you want correct date or time stored in memory with test result). See page 14.

Materials Needed:

Meter with Test Sensor Disc inserted



1. To enter the Test Mode, move Pad left and hold while moving the Slide forward. Be sure Slide is moved all the way to the end. A Test Sensor appears and the display prompts blood application with a flashing drop ♦.



If a **Programme Number** (P1 to P62) appears, press **Button B** to change (if needed) and then **Button A** to continue. If no change press **Button A** to prompt blood application. **Programme Number** appears in display if **Meter** has been opened since last used.

2. Prick your finger with the **Microlet Device** and form a small drop of blood.











3. Hold your finger level with the drop of blood on top. Bring the **Meter** in from the side to the drop of blood.

Let the entire front edge of the **Test Sensor** touch the surface of the blood drop. Blood is automatically drawn into the inside of the **Test Sensor**. Hold there until **Test Sensor** is filled and you hear a beep. If you do not wish to store a result, then press Button B before closing the Slide. An X appears on the display.

Deleted results appear in the memory, marked with an **X**. These results are deleted from the average of stored test results.

5. Point Meter down (over waste container) and move Slide back all the way to the end. The Test Sensor is released.

NOTE: Test results are stored automatically when **Slide** is closed.





Do not apply blood directly from an above position.

4. The test result displays after 30 seconds.



Note: The Meter automatically turns off if it is left on for 3 minutes (without sensor) or 15 minutes (with sensor) with no activity. To preserve the battery life, remember to turn off the **Meter** after you have used it.

IMPORTANT: If your glucose level is below 2.8 mmol/L or above 13.9 mmol/L, test again. If your glucose level is **still** below 2.8 mmol/L or above 13.9 mmol/L, it may indicate a potentially serious medical condition. We recommend you consult your physician or healthcare professional immediately.





- **WHEN:** Anytime you want to check performance of the system (Meter, Test Sensor Disc or your testing technique).
- WHY: If the test result is not within range, there may be a problem with the **Test Sensor** or the **Meter**. See page 33.

Materials Needed:







with Control Range

Control Meter with Test Sensor Solution Disc inserted

1. Move Pad left and hold while moving the Slide forward. Be sure Slide is moved all the way to the end. A Test Sensor appears and the display prompts for application of the sample with a flashing drop ♦.

If a **Programme Number** appears, press **Button B** to

change (if needed) and then **Button A** to continue. If no change, press **Button A** to prompt sample application.

Programme Number appears in display if **Meter** has been opened since last used.

2. Squeeze a drop of control solution onto a clean surface.







3. Bring the **Meter** in from the side to the drop of control solution. Let the entire front edge of the **Test Sensor** touch the surface of the control solution drop. Hold there until the **Test Sensor** is filled with solution (you will hear a beep).

4. The test result displays after 30 seconds. Press the **B Button** twice to mark the test result with a "tick" (\checkmark) when stored in the memory. Marked control tests will not be included in any averages.



5.8[~]

Compare the test result to the range listed on the end flap of the specific **Test Sensor** carton being used.

Note: The Control Solution contains a red dye which may stain.



5. Point the **Meter** down (over waste container) and move **Slide** back **all the way to the end.** The **Test Sensor** is released to be discarded.



The Features Mode



To Turn the Meter On in the Features Mode:

Move Slide forward.

Button A: Allows you to move to the next setting.

Button B: Allows you to change the setting.

Anytime you enter the Features Mode, the following information is always displayed automatically and in this order. 1. The number of remaining $Pate = \frac{24.11}{24.11}$

1. The **number of remaining Test Sensors** left in your **Meter** appears with the present *time* and *date*.

2. The **last two test** *results* appear with the time and date of the test.



NOTE:

If the Meter is new and no test results are stored in memory, the Meter will display the number of remaining sensors only.

3. After reviewing the above information, turn the **Meter** off.



6 CHAPTER Set Time and Date

To set the time and date, follow these directions.

1. Move **Slide** forward to enter **Features Mode**.

2. Press and release **Button A** (average displays if test results are in memory).

If no blood glucose test results are in memory, the *number of remaining* **Test Sensors** flashes.

If the number of **Test Sensors** is not correct, press **Button B** to change and then go on to Step 3.

If test results are in memory, press and hold **Button A.** The *number of remaining* **Test Sensors** flashes.

Press **Button B** if you want to change the number and then go on to Step 3.



3. Press and release **Button A** — the minute flashes. Press **Button B** to make a change.





4. Press and release **Button A** — the hour flashes. Press **Button B** to make a change.

- **5.** Repeat step 4 to set:
- ∎ day
- month
- ∎ year

6. Move the **Slide** back to turn **Meter** off.





The Meter calculates four time-specific averages identified as A 1, A 2, A 3, and A 4. These times are preset for meal times but may be changed to meet your schedule. To be included in the average, the testing time must occur within one hour before or after the specific set time.

The preset times are:

81	6:00	83	18:00
5.8	12:00	84	21:00

PROCEDURE:

1. Move Slide forward to enter Features Mode.

2. Press and release Button A. Average displays if three test results have been stored.

Press and hold **Button A** until number of remaining sensors appears. Press and release Button A-time appears.

3. Press and hold **Button** A until A 1 appears. Release Button A. The minute flashes.

4. Press Button B to change the minute for the A 1 Time-Specific Average.





5. Press and release Button A. The hour flashes.

Then press Button B to change the hour.



6. Press and release Button A again and move to A 2 Average.

Press Button B to change the minute. If you want to continue changes for A 2, A 3 and A 4, repeat steps 5 through 6. Then move Slide back to turn Meter off.



If you only want to change a specific time(s), press Button A repeatedly to scroll to that display.

The basic features are preset but may be reset to fit your needs:

- from beeper on to beeper off.
- from mmol/L to mg/dL blood glucose units.
- from a 24 hour to a 12 hour (am/pm) time clock.
- from Celsius (C) to Fahrenheit (F) temperature units.

PROCEDURE:

1. Move Slide forward to enter Features Mode.

If a **Programme Number** appears and needs to be changed, see page **4** (**#5**).

2. Press and hold **Button A** four times.

3. Then press and hold **Button A** until "**b**" (beeper) appears. Release **Button A** and go on to Step 3 (next page).





BEEPER SETTING:

4. Press **Button B** to make the change and press **Button A** again to move to the next feature.



OPTIONAL SETTINGS: (Repeat #4 to change settings)



5. Move Slide back to turn Meter off.



TIME-SPECIFIC AVERAGES

The average of all blood glucose results and the time-specific averages are based on a two-week testing period. A minimum of three tests must be run within a two-week period to give an average. For example: if three tests are run within two weeks for A 1 and A 4 time periods only, then A 2 and A 3 will not display in your review.

1. Move **Slide** forward to enter **Features Mode**. The number of remaining **Test Sensors** displays and the last two test results.

2. Press and hold **Button A.** The first display shows the two-week average of all glucose results.



3. Press **Button B**; two displays follow showing the A 1 average test result.



4. Press **Button B** again and the **A 2** average displays. Continue to press **Button B** after each two (successive) displays to show the remaining averages.





5. Move Slide back to turn the Meter off or continue to review stored test results. See next page, step 3.

NOTE:

■ If no average is available for a specific time (there must be at least 3 stored blood glucose test results in the last two weeks), the display scrolls to the next available Time-Specific Average. If there are no averages stored, the first result shown will be the last test result (see Chapter 10).



TEST RESULTS

1. Move Slide forward to enter Features Mode.



2. Press and hold **Button A** (average displays).



3. Press **Button B** to review any average results and all other stored test results (beginning with the latest result). Continue to press and release **Button B** or hold to scroll through all stored test results.

A beep signals the last test result and returns to original display.



ERASE ALL TEST RESULTS

You can erase all test results stored in the Meter if you press and hold both **A** and **B Buttons** while reviewing stored test results (#3/Chapter **10**).



However, you must press the buttons before the beep signals the last test result.

Press and hold **both Buttons** until **"000"** appears (about 5 seconds). If you change your mind, to cancel erasing — press **either Button** before closing the **Slide**.

When the **Slide** is moved back, all stored test results are erased.





12 CHAPTER Transfer to a Computer

- Your **Meter** can transfer test results to a computer where results can be electronically summarized in a logbook report, graph or chart.
- To make use of this feature, you need special software and a connecting cable.
- For more information relating to this program, contact your nearest Bayer Diagnostics office.



EXTERIOR CLEANING PROCEDURE

The exterior of the **Meter** can be cleaned using a moist (not wet) lint-free tissue with a mild detergent or disinfecting solution.* Wipe dry with lint-free tissue after cleaning.

*1 part bleach mixed with 9 parts water.

INTERIOR CLEANING PROCEDURE

The Latch: Open Meter and wipe inside of Latch with moist tissue and dry thoroughly.

The Test Sensor Guide: Gently wipe any moist area on Test Sensor Guide and nearby areas with dry tissue.

It is important to avoid excessive water. The electronics may be affected.





WARNING: POTENTIAL BIOHAZARD: Healthcare professionals using this system on multiple persons should be aware of the following, and should follow the infection control procedure approved by their laboratory facility. All products or objects which come into contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.

The user should follow the recommendations for prevention of blood-borne transmissible diseases in healthcare settings, as recommended for potentially infectious human blood specimens in the Health Service Guidelines on Decontamination of Equipment prior to inspection service or repair, Ref. HSG. (93) 26.



BATTERY REPLACEMENT

1. Locate the Battery Capsule.



2. Using a fingernail, thin coin or similar object, pry the capsule loose and lift from **Meter**.



3. Push through the small semicircular hole to release the two batteries.



4. Insert two new lithium batteries (CR2016) into the **Battery Capsule** with the + side on top. Push down gently to lock them into place.





5. Replace the **Battery Capsule**.

IMPORTANT:

Remember to reset date and time before running another test. See page 14 for directions.



WARNING:

- Keep batteries away from children.
- Lithium batteries are poisonous.
- If swallowed, immediately contact your physician.
- Discard batteries according to your local environmental regulations.

14 CHAPTER Problem Solving / Error Codes

CAUSE / SOLUTION



■ Replace batteries (two lithium batteries — size CR2016). See directions — page 26.



Temperature:

- too cold (below 0° C)
- too hot (above 50° C).
- Use Meter in an area of correct operating temperature (10° to 40° C).



Test Sensor removed during the test.

■ Move Slide back to turn the Meter off and then repeat the test.



Meter is turned on when the End Latch is open.

■ Move Slide back (close) to turn the Meter off and then close the End Latch.

Err possible

causes

CODE

CAUSE / SOLUTION

- Meter has detected an error; accurate results not possible:
- Test Sensor Guide is wet. Clean inside of Meter (page 25). Be sure inside is dry before reuse.
- Blood applied before Meter is ready. Repeat test, making sure blood icon displays.
- Test Sensor has been damaged due to intense heat exposure.
 If problem cannot be corrected, call the Customer Service
 Department or 1-800-028-251 (toll free).



Meter has malfunctioned.

Call the Customer Service Department or 1-800-028-251 (toll free).



CAUSE / SOLUTION



- Test Result is below 0.6 mmol/L.
- Meter has detected an error. Repeat the test and make sure Test Sensor is filled.

CODE CAUSE / SOLUTION

- LO`C Temperature is too low (between 0° and 10° C) and could affect test results.
 - Test within operating temperature range (10° to 40° C).



Test Result is above 33.3 mmol/L.

Repeat the test. If still high, contact your physician or diabetes educator regarding a possible hyperglycemic condition (high blood sugar).



Temperature is too high (between 40° to 50° C) and could affect test results.

■ Test within operating temperature range (10° to 40° C).



Deleted Test Result

If the temperature is too low or too high, the test result is marked with an X and deleted from the average.



Low Batteries

Replace batteries within one week or 20 readings.



Problem Solving / Meter and Test Sensor

PROBLEM

SOLUTION

1. The display goes blank when the **Meter** is turned on.

NOTE: Display goes blank if **Meter** is left on for 3 minutes (without sensor) or 15 minutes (with sensor) and no activity.

2. Some display segments do not appear in the full display when the **Meter** is turned on.

3. Meter fails to start countdown after blood is applied.

■ Check Battery Capsule to be sure it is tightly in place. If Battery Capsule is secure and display is still blank, replace batteries (two lithium — CR2016). See page 26.

■ Call the Customer Service Department or 1-800-028-251 (toll free).

■ Retest. If the countdown fails to start, call the Customer Service Department or 1-800-028-251 (toll free).

PROBLEM

4. Control Test result is out of range (too high or too low).

Causes:

- Test Sensor or control solution passed expiration date or shelf life date.
- Deteriorated **Test Sensor** due to heat or cold.
- Control solution not at room temperature.
- Not enough control solution drawn into **Test Sensor.**

SOLUTION

■ Make sure correct **Programme Number** has been entered.

Run another control test. If still out of range, retest with a new **Test Sensor Disc** and/or control (if needed) with an acceptable expiration date and shelf life. If still out of range, call the Customer Service Department or 1-800-028-251 (toll free).



CUSTOMER SERVICE

If attempts to correct a problem fail, please call the Customer Service Department or 1-800-028-251 (toll free). We have trained specialists to assist you.

IMPORTANT:

- Speak to a Customer Service Representative before returning your Meter for any reason. Information needed to resolve your problem correctly and efficiently will be provided.
- Have your Glucometer[®] ESPRIT[™] Meter ready for testing when you phone. It would also be helpful to have a bottle of Glucometer[®] ESPRIT[™] Normal Control available.
- Fill out the following check list before calling:

CHECK LIST:

- 1. The meter serial number is:
- 2. The date and time the problem occurred was:
- 3. I have tested with the Normal Control:
 Yes_____ No_____

 The Normal Control result was:_______
 Lot Number:

 Exp. Date:
 Exp. Date:
- 4. Please include the lot number and expiration date of the Test Sensor Disc currently being used. This information is printed on the Test Sensor and the Test Sensor Disc Carton.

Lot Number:_____ Exp. Date:_____

SPECIFICATIONS:

Test: Capillary blood glucose Referenced to whole blood

Sample Size: Approximately $3 - 4 \mu L$

Operating Range: 0.6-33.3 mmol/L

Testing Time: 30 seconds

Memory Features: Stores last 100 test results.

Note: If 100 test results are stored in memory and a new one is added, the oldest test result is automatically discarded.

Temperature: 10° to 40° C

Humidity: 10 to 80% RH

Power Source: Two 3-volt lithium batteries (CR2016)

Battery Life: Approximately 1000 tests

CE Certification: This device conforms to EMC Directive 89/336 amendment 92/31/EEC.

Patent # 5,429,735/MSE #1866 – EPO Appl. #951091990 Patent # 5,575,403/MSE #1868 – EPO Appl. #961002086



REPLACEMENT PRODUCTS:

When calling or writing for supplies, be sure to include the number with the name of the replacement part or product.

<u>Part Number</u> *	ltem
40030032	3-volt Lithium Battery (DL or CR 2016) — 2 (Available at most stores)
99939679 50184147	Glucometer® ESPRIT™ User Guide Glucometer® ESPRIT™ Quick Reference Guide

*Part Numbers subject to change without notice.

Product	
<u>Number</u>	Product Name
3616	Glucometer [®] Esprit™ Test Sensor Discs — 50s
3649	Glucometer [®] Esprit™ Low Control
3650	Glucometer [®] Esprit™ Normal Control
3651	Glucometer [®] Esprit™ High Control
6541	Microlet [™] Automatic Lancing Device
5970	Glucolanz™ Lancets (200s)
6555	Microlet™ Endcaps — Regular (10s)
6559	Microlet™ Endcaps — Super (10s)

Replacement products may be obtained from Diabetes Care Centers, or your local pharmacy.

Glucometer[®] Esprit[™] System (Whole Blood Referenced)

1. Accuracy: A patient-use clinical study was performed at diabetes care centers in three different locations. Glucose levels were measured with the Glucometer ESPRIT System on over 300 fresh capillary blood specimens by 61 persons with diabetes, and six healthcare professionals. The results were compared with the whole blood glucose results of the YSI 2300 Stat Plus (Yellow Springs Instrument Co., Inc., Yellow Springs, OH), a glucose oxidase/electrode system.

Figure 1 on the following page shows the comparison of the lay diabetic Glucometer ESPRIT System results with the whole blood glucose results. The comparison of the healthcare professional results with the whole blood glucose results is shown in *Figure 2*.



Patient Use Clinical Study Results

Figure 1 Glucometer ESPRIT System Results Obtained By 61 Lay Diabetics.



Figure 2 Glucometer ESPRIT System Results Obtained By 6 Healthcare Professionals.



Glucometer ESPRIT System (Whole Blood Referenced)

2. Precision: Precision Results for Whole Blood Specimens: EDTA anticoagulated glycolyzed whole blood pools were supplemented with glucose to obtain five glucose levels. Multiple replicates of the whole blood were tested on one day by multiple operators using multiple Glucometer ESPRIT meters and one lot of sensors. The whole blood glucose levels of the blood specimens were also tested using the YSI 2300 Stat Plus Glucose Analyzer, a glucose oxidase method. The accuracy of the YSI was verified using control sera assayed using a modification of the CDC hexokinase reference procedure (HEW publication no. [CDC] 77-8330).

YSI		Glucometer ESPRIT Results						
Mean Whole Blood Glucose mg/dL (mmol/L)		No. of Tests	N mg/dL	1ean . (mmol/L)	Bias	S mg/dL	D (mmol/L)	C V (%)
21	(1.17)	78	19	(1.05)	–2 mg/dL or –0.11 mmol/L	2.6	(0.14)	13.8
49	(2.72)	78	48	(2.66)	- 1.8%	3.2	(0.18)	6.7
102	(5.66)	80	103	(5.72)	0.9%	3.7	(0.21)	3.6
192	(10.65)	79	192	(10.65)	0.0%	6.4	(0.36)	3.3
376	(20.87)	80	382	(21.20)	1.6%	10.2	(0.57)	2.7
566	(31.41)	80	593	(32.91)	4.8%	16.2	(0.90)	2.7

Precision Results for Controls: The Glucometer ESPRIT Control solutions were tested in triplicate twice per day for ten days by one operator using one meter and one lot of sensors. The following precision results were obtained:

	Glucometer ESPRIT Results						
		Within-run		Total			
Control	Mean mg/dL (mmol/L)	S D mg/dL (mmol/L)	C V (%)	S D mg/dL (mmol/L)	C V (%)		
Low	69 (3.83)	2.7 (0.15)	3.9	3.5 (0.19)	5.1		
Normal	127 (7.05)	4.7 (0.26)	3.7	5.7 (0.32)	4.5		
High	372 (20.64)	5.7 (0.32)	1.5	7.1 (0.34)	1.9		



TRADE PRACTICES ACT WARRANTIES

The Purchaser of this equipment is entitled to broad warranties, rights and remedies conferred on consumers by the Trade Practices Act which cannot be restricted, modified or excluded.

ADDITIONAL BAYER AUSTRALIA LTD. WARRANTY

- If (i) a defect in workmanship or materials not due to accident, abuse or use of unauthorized attachment occurs within five years of purchase, and
 - (ii) Bayer Australia Ltd. is not already obligated to rectify the defect under the Trade Practices Act warranties, and
 - (iii) the warranty card is completed and returned to Bayer Australia Ltd. within 10 days after purchase then Bayer Australia Ltd. will at its discretion repair or replace the equipment or supply equivalent goods free of charge.

The Purchaser should note that the requirement to return the warranty card relates only to the additional Bayer Australia Ltd. warranty and is NOT a requirement for the Purchaser's warranties, rights and remedies under the Trade Practices Act. The liability of Bayer Australia Ltd. for breach of the additional Bayer Australia Ltd. warranty is limited to the replacement or repair of the equipment or the supply of equivalent equipment and liability for consequential damage is expressly excluded.

Should you require service for your Glucometer[®] ESPRIT[™] Blood Glucose Meter, please ensure that it has been maintained as recommended in the User Guide. If BAYER AUSTRALIA LTD. finds any malfunction due to the accumulation of dried blood, serum or any foreign matter in or on the meter, resulting from the failure of the Purchaser or user to adequately maintain the Glucometer ESPRIT meter, a minimum of \$60.00 will be charged for cleaning and servicing.

Bayer Australia Ltd., (ACN 000 138 714) 875 Pacific Hwy., Pymble NSW 2073, Australia